

REMARKS

1. In response to the Office Action mailed July 9, 2008, Applicants respectfully request reconsideration. Claims 1-6, 8-17, 20, 21, 24-26 and 28-62 were last presented for examination. In the outstanding Office Action, claims 1-6, 8-17, 20-21, 24-26, and 28-62 were rejected. By the foregoing Amendments, claims 1, 24, 29 and 59 have been amended. No claims have been added and no claims have been cancelled. No new matter has been added. Upon entry of this paper, claims 1-6, 8-17, 20-21, 24-26, and 28-62 will be pending in this application. Of these fifty-six (56) claims, 4 claims (claims 1, 24, 29 and 59) are independent.

2. Based upon the above Amendment and following Remarks, Applicants respectfully request that all outstanding objections and rejections be reconsidered, and that they be withdrawn.

Priority Claim

3. Applicants note with appreciation the Examiner's acknowledgement of foreign priority under 35 U.S.C. §119.

Claim Rejections under §103

4. Claims 1-3, 8, 14-17, 20, 24, 28-30, 32-35, 39 and 45-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,119,044 to Kuzma ("Kuzma") in view of U.S. Patent No. 1,146,292 to Wappler ("Wappler"). (*See*, Office Action, pg. 3, ¶ 3;) Claims 5, 6, 12, 13, 37, 38, 43-44 and 59-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,119,044 to Kuzma ("Kuzma") in view of U.S. Patent No. 1,146,292 to Wappler ("Wappler"). (*See*, Office Action, pg. 6, ¶ 16) Applicants respectfully request that the Examiner reconsider and withdraw these rejections for at least the following reasons.

The Combination of Kuzma and Wappler is prima facie Improper

5. The proposed combination of Kuzma and Wappler is *prima facie* improper because the Examiner has failed to provide an appropriate basis for making the proposed combination. As stated by the Supreme Court in *KSR International Co. v. Teleflex Inc.*, "a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was,

independently known in the prior art.” (127 S.Ct. 1727, 1741 (2007).) The Supreme Court recognized that “rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some *articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.*” (See *KSR*, 127 S.Ct. at 1741 (citing *In re Kahn*, 441 F.3d 977, 988 (C.A.Fed. 2006); emphasis added.) Applicants submit that the Examiner has completely failed to satisfy these legal obligations. The Examiner has done what has been viewed as circumspect by the Supreme Court and has only provided a conclusory and unsupported statement to justify the proposed combination of Kuzma and Wappler.

6. Kuzma is directed to an implantable electrode array adapted to be inserted into the cochlea, and which assumes a shape to hug the modiolar wall of the cochlea after insertion. A naturally curved positioning stylet made of shape-memory metal is cooled into a straight shape and inserted into the electrode array. As the stylet warms to body temperature, it returns to its spiral memory shape, causing the electrode array to also assume a spiral shape, thus positioning the electrode contacts against the modiolar wall. (See, Kuzma, Abstract.) FIG. 4 of Kuzma shows an electrode array which was formerly straight (shown as broken lines) but is now in a curved configuration. Kuzma further states that “soft tip 37, having a depth of distance L8, is typically formed from LSR-25 at the very distal tip of the electrode array 30. In the preferred embodiment, L8 has a value of approximately 0.3 mm.” (See, Kuzma, col. 11, ll. 39-42.)

7. Wappler describes a system for healing morbid organs by exposing the organ tissue to “nitrous oxid, ozonous and kindred gases” that are formed in a chamber. (See, Wappler, pg. 1, ll. 78-83.) Wappler describes prior systems utilizing glass electrodes which were liable to break during or after insertion into a human body. (See, Wappler, pg. 1, ll. 15-23.) In the Wappler invention, a glass tube 10 is surrounded by perforated metallic sheath conductor 14. (See, Wappler, pg. 1, ll. 45-58.) Disposed within the length of glass tube 10 is a conductive coating 12 made of tinfoil. Coating 12 made contact with a metal cap 13, to which electricity is applied. Surrounding metallic sheath 14 around glass tube 10 forms an air chamber 17 between metallic sheath 14 and glass tube 10. When electricity is applied to metal cap 13, the electricity is said to flow via coating 12 through dielectric body 10 to ionize the air in the chamber 17 to form nitrous oxid[e], ozonous and kindred gases are formed that pass through the perforated metallic

sheath conductor 14 to provide healing to the morbid organs. (*See*, Wappler, pg. 1, ll. 45-83.) Clearly, in Wappler, both the metal cap 13 (the tip of the Wappler sheath) and the metallic sheath conductor 14 which surrounds glass tube 10 is metallic and not flexible. Therefore, any resistance to foldover in Wappler is due to the fact that the material used for those parts are metallic and not flexible, and not due to its flexibility and configuration so as to resist foldover.

8. In the Office Action, the Examiner states that Kuzma teaches substantially Applicants' invention as claimed, but admits that Kuzma "fails to teach a conical tapered portion tapering and extending distally from the distal end of the electrode array." (*See*, Office Action, pg. 5, ¶ 15.) The Examiner then asserts that Wappler teaches that "it is known to have a conical tapering at the distal end of an electrode array... for providing the predictable results of preventing fold-over of the tip member and also facilitating insertion of the electrode array." (*See*, Office Action, pg. 5, ¶ 15.) The Examiner relies on Wappler as teaching a conical tapering distal end of an electrode array, asserting that it would have been obvious to modify the Kuzma device to have a conical tapered portion at the distal end. The Examiner attempts to support this assertion by further asserting that "such a modification was known in the art to provide the predictable results of preventing fold-over of the tip member and also facilitating insertion of the electrode array and providing a more rigid support to facilitate placement." (*See*, Office Action, pg. 5, ¶ 15.) However, the Examiner provides nothing more than this conclusory statement as support.

9. Applicants assert that, in fact, one having ordinary skill in the art would not have been motivated to modify Kuzma in view of Wappler, as suggested by the Examiner. As explained above, Kuzma required that its electrode array as well as its tip be flexible such that it could follow the modiolar wall when implanted but not so flexible so as to allow foldover during insertion of the array into the cochlea. However, instead of being a flexible electrode array, Wappler discloses an electrode which is said to not only have a metal "tip electrode" but wherein almost the entire electrode array is said to be metallic (a metal sheath surrounding an inner tube). Therefore, one of ordinary skill in the art would not have been motivated to modify Kuzma with the teachings of Wappler, namely the shaping of the Kuzma tip so as to be more like the tip in Wappler since an electrode array encased in a non-flexible sheath would not inform a person having ordinary skill how to configure the flexible electrode array of Kuzma

with Wappler so as to prevent foldover, when the foldover preventative aspect of Wappler is derived from the fact that its body is formed of inflexible metal rather than the configuration of the flexibility of the Kuzma's flexible tip. Because, as explained above, the Examiner has completely failed to provide any rational underpinning to justify the proposed combination, Applicants assert that the proposed combination of Kuzma with Wappler is *prima facie* improper and that the rejections under 35 U.S.C. §103 should be reconsidered and withdrawn.

***The Proposed Combination of Kuzma and Wappler
is based on Impermissible Hindsight***

10. Applicants further assert that the combination of Kuzma and Wappler is *prima facie* improper because the reasoning provided by the Examiner to combine the cited references is based on impermissible hindsight. As stated in Section 2142 of the Manual of Patent Examining Procedure (M.P.E.P.), the “[E]xaminer must step backward in time and into the shoes worn by the hypothetical ‘person of ordinary skill in the art’ when the invention was unknown and just before it was made.” The Examiner must then examine the claimed invention and determine whether the invention as a whole would have been obvious to that hypothetical person. (See, M.P.E.P., §2142.) Although this is inherently an analysis based on hindsight, “impermissible hindsight must be avoided and the legal conclusion must be reached on the basis of the facts gleaned from the prior art.” (See, M.P.E.P., §2142.) The Examiner must consider only the prior art, and knowledge derived from Applicants’ disclosure must be put aside in reaching this determination. (See, *In re McLaughlin*, 443 F.2d 1392, 1395 (CCPA 1971).)

11. As described above, Kuzma is directed to an implantable electrode array adapted to be inserted into the cochlea, and which assumes a shape to hug the modiolar wall of the cochlea after insertion. (See, Kuzma, Abstract.) There is absolutely no teaching or suggestion in Kuzma, or the other art of record, that would lead one of ordinary skill in the art to incorporate an inflexible metal tip, whether shaped to be conically tapering, where the body of the electrode array is encased in an inflexible metal sheath. Such incorporation of an inflexible metal tip which is said to be used in conjunction with an inflexible metal sheath body would fundamentally frustrate or prevent the usage of the flexible electrode array of Kuzma in a way that would destroy the purpose for which Kuzma is intended. Therefore, Applicants assert that the Examiner has based the proposed combination of impermissible hindsight drawn directly

from Applicants' disclosure, piecing together features of various references in an attempt to produce Applicants' claimed invention. Accordingly, Applicants assert that the combination of Kuzma and Wappler is *prima facie* improper, and that the rejections under 35 U.S.C. §103 should be withdrawn.

***The Proposed Combination Still Fails to Contain
All Elements of Applicants' Claimed Invention***

12. As set forth in §2142 of the M.P.E.P., "to establish a *prima facie* case of obviousness... the prior art reference (or references when combined) must teach or suggest all of the claim limitations." Applicants respectfully assert that even if the references were combined as proposed by the Examiner, the resulting combination would still fail to teach all elements of Applicants' claimed invention.

13. As explained in detail above, Wappler is directed to a glass tube 10 surrounded by perforated metallic sheath conductor 14. (*See*, Wappler, pg. 1, ll. 45-58.) Disposed within glass tube 10 is a conductive coating 12 made of tinfoil which is electrically connected to metal cap 13, to which electricity is applied. Metallic sheath 14 surrounds glass tube 10, thereby forming an air chamber 17 between metallic sheath 14 and glass tube 10. Clearly, both the metal cap (or tip) 13 and metallic sheath 14 have no flexibility, and their construction of metal and its lack of flexibility is responsible for any foldover prevention provided therefrom. In other words, even assuming that one of skill in the art were motivated to combine Kuzma with Wappler for the reason stated by the Examiner, namely to prevent foldover, the feature providing this supposed benefit that would be incorporated into the Kuzma electrode array would be the fact that the tip is a metal cap.

14. In contrast, Applicants' independent claim 1 recites, in part, "a tip member comprising a ***conical tapered portion***... wherein said tip member is configured such that ***the dimensions and shape of said flexible conical tapered portion of said tip member prevents substantial foldover of said tip*** when a deflection/impact force is applied to said tip member during implantation into the cochlea." (*See*, Applicants' claims 1 and 24, as amended above; emphasis added.) Applicants assert that even if the inflexible metal tip of Wappler were to be combined with the Kuzma device for the reason given by the Examiner, the combination would result in a device which fails to teach or suggest all claim limitations of Applicants' claimed invention.

15. Furthermore, Applicants' independent claims 29 and 59 recite, in part, "such that *the dimensions and shape of said conical tapered portion of said tip member causes at least a portion of said tip member to operate* as a constant-strength *cantilever beam* when the deflection/impact forces are applied to said tip member during implantation." (See, Applicants' independent claim 29, as amended above; emphasis added.) Similarly, independent claim 59 recites, in part, "such that *the dimensions and shape of said conical tapered portion of said tip member prevents substantial foldover* of said tip member when a deflection/impact force is applied to said tip member during implantation." (See, Applicants' independent claim 59, as amended above; emphasis added.) Clearly, with both independent claims 29 and 59, Applicants' tip is dimensioned and shaped so as to be flexible to provide the benefit described. To the contrary, the inflexible metal tip feature of Wappler, even if properly combined with the flexible electrode array of Kuzma, is formed of a material that enables it to maintain its rigidity, and in fact is part of a unitary device that is designed to not flex.

16. Therefore, for at least the reasons presented above, and based on Applicants' presently presented Amendments, Applications assert that neither Wappler nor Kuzma, alone or in combination with each other or any other art of record, teach all elements of Applicants' claims 1, 24, 29 and 59, and therefore the rejections under Section 103 of these claims are improper. Accordingly, Applicants respectfully request that these rejections be reconsidered and that they be withdrawn.

Dependent claims

17. The dependent claims incorporate all the subject matter of their respective independent claims and add additional subject matter which makes them independently patentable over the art of record. Accordingly, Applicants respectfully assert that the dependent claims are also allowable over the art of record.

Conclusion

18. In view of the foregoing, this application should be in condition for allowance. A notice to this effect is respectfully requested.

19. Applicants reserve the right to pursue any cancelled claims or other subject matter disclosed in this application in a continuation or divisional application. Any cancellations and amendments of above claims, therefore, are not to be construed as an admission regarding the patentability of any claims and Applicants reserve the right to pursue such claims in a continuation or divisional application.

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